Are causality assessments being done by CDC or WHO?

FOIA request says NOPE.

Jessica Rose
Jul 5

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Once upon a time there was a recent FOIA request made that led nowhere. No! This isn't the story of the PRR! This is *another* story of a nowhere lead. It seems to be par for the course these days, doesn't it? Thanks to all the hard-working people requesting this information via FOIA, and also to all of the people trying to *find* the requested information in the piles of well, nothing. I guess it's not that hard to sift through nothing.

Background

There are two documents that mention assessment of causality using adverse event data: "**Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification, 2nd ed., 2019 update**" (**World Health Organization** (WHO)) and the "**Standard Operating Procedures" (SOP) document updated Jan 29, 2021**" (**Centers for Disease Control** (CDC)).

Acronyms to know:

1. FOIA: Freedom of Information Request
2. AE: Adverse Event
3. AESI: Adverse Event of Special Interest
4. AEFI: Adverse Event Following Immunization
5. SOP: Standard Operating Procedures
6. CDC: Centers for Disease Control
7. WHO: World Health Organization

CDC - The latter has a description of causality assessment protocol that goes like this:

> **2.0 Overview of VAERS Surveillance Activities**
> The specific tasks and frequency of these tasks for surveillance will be adjusted to meet public health needs, with consideration of staff time and resources. For example, in the event of a significant increase in the number of adverse events (AEs) reported to VAERS that warrant clinical review, additional ISO staff will be assigned to perform reviews. An algorithm of the process to monitor vaccine AEs is shown in **Appendix 4.1**.
>
> CDC will perform clinical reviews for AESIs listed in Table 1. Results from automated data assessment will identify additional conditions potentially warranting further clinical review.

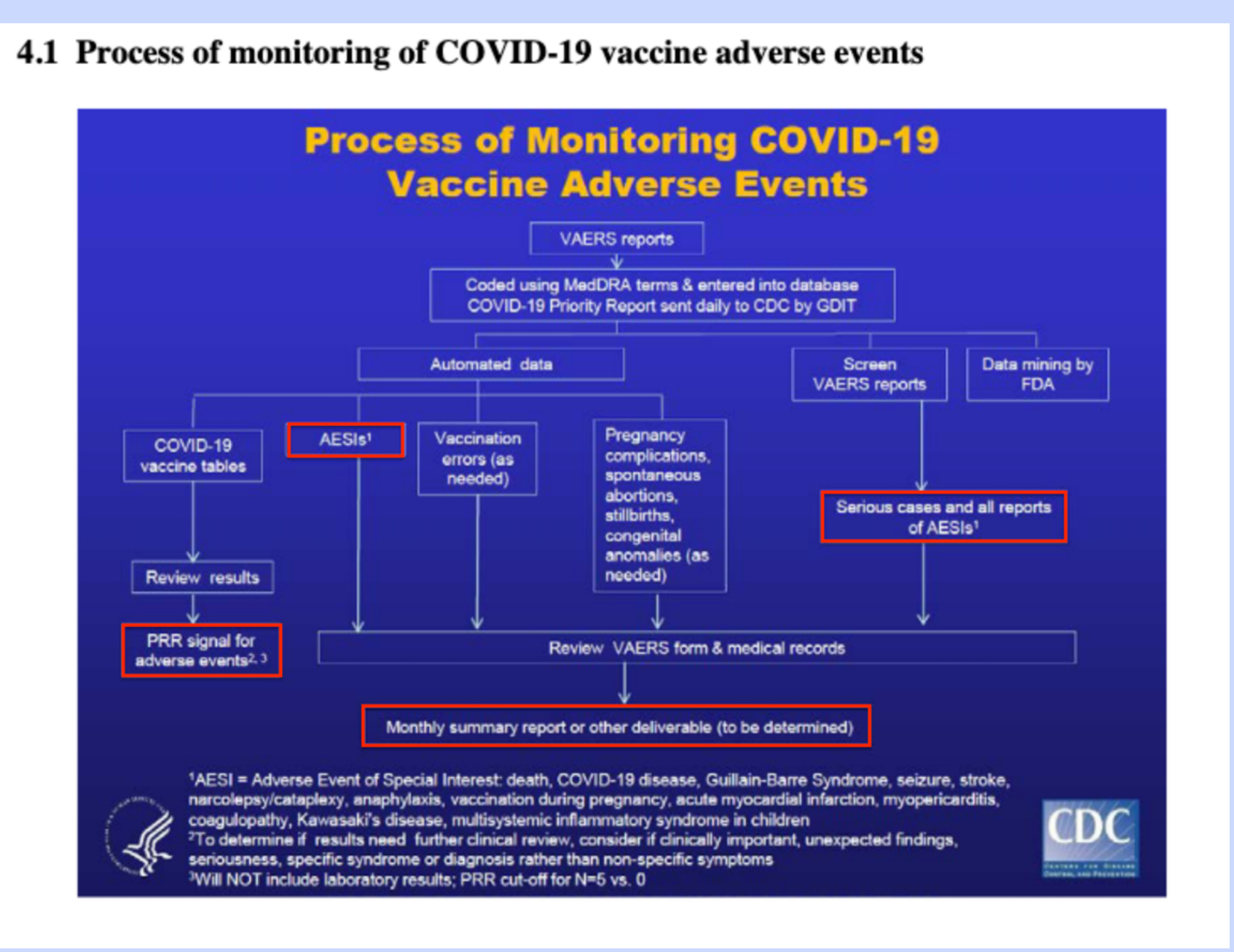
Table 1 includes the following AESIs: Acute myocardial infarction (AMI), Anaphylaxis, Appendicitis, Bell's Palsy, Coagulopathy, COVID-19, Death, Guillain–Barré syndrome, Kawasaki's disease, Multisystem Inflammatory Syndrome in Children (MIS-C), Multisystem Inflammatory Syndrome in Adults (MIS-A), Myopericarditis, Narcolepsy/Cataplexy, Vaccination during pregnancy, Seizure, Stroke, Transverse myelitis. Pretty short list, but alright.

Thus, it is written in this document updated on January 29, 2021, that the AEs listed above would be clinically-reviewed by the CDC to identify conditions warranting further review, ie: causality assessment.

For my splendid readers, the VAERS reports without considering an Under Reporting Factor (URF) (as of July 1, 2022) are as follows. These counts are bound to be *drastically* underestimated (due to many factors such as multiple MedDRA codes for the same AE), and do not forget the URF. I have added the AE counts as they would be with an URF of 31 in brackets (URF of 10 for death) as well. Check out COVID-19.

1. Acute myocardial infarction (AMI): 6,090 (188,790)
2. Anaphylaxis: 9,526 (295,306)
3. Appendicitis: 1,560 (48,360)
4. Bell's Palsy: 6,582 (204,042)
5. Coagulopathy: 516 (15,996)
6. COVID-19: 608,213 (**18,854,603**) - This is ironic, Alanis. Why don't you sing about this? By the way, this is #1 reported AE in VAERS currently.
7. Death: 32,671 (w/URF 10 = 320,671)
8. Guillain–Barré syndrome: 2,319 (71,889)
9. Kawasaki's disease: 46 (1,426)
10. Multisystem Inflammatory Syndrome in Children (MIS-C): 90 (2,790)
11. Multisystem Inflammatory Syndrome in Adults (MIS-A): 22 (682)
12. Myopericarditis: 37,803 (**1,171,893**)
13. Narcolepsy/Cataplexy: 178 (5,518)
14. Vaccination during pregnancy: 9,674 (299,894)
15. Seizure: 14,303 (443,393)
16. Stroke: 16,520 (512,120)
17. Transverse myelitis: 325 (10,075)

Appendix 4.1 is a schematic of the algorithm meant to be implemented to do these assessment and reviews as shown in Figure 1. You'll note in red that the assessment of listed AESIs is part and parcel as part of the steps in the algorithm. You'll also notice that the PRR signal is meant to be measured here. We all know by now that they also are not assessing the PRR thanks to that other FOIA request.


4.1 Process of monitoring of COVID-19 vaccine adverse events

Process of Monitoring COVID-19 Vaccine Adverse Events
VAERS reports
Coded using MedDRA terms & entered into database COVID-19 Priority Report sent daily to CDC by GDIT
Automated data
Screen VAERS reports
Data mining by FDA
COVID-19 vaccine tables
AESIs¹
Vaccination errors (as needed)
Pregnancy complications, spontaneous abortions, stillbirths, congenital anomalies (as needed)
Serious cases and all reports of AESIs¹
Review results
PRR signal for adverse events²,³
Review VAERS form & medical records
Monthly summary report or other deliverable (to be determined)
CDC

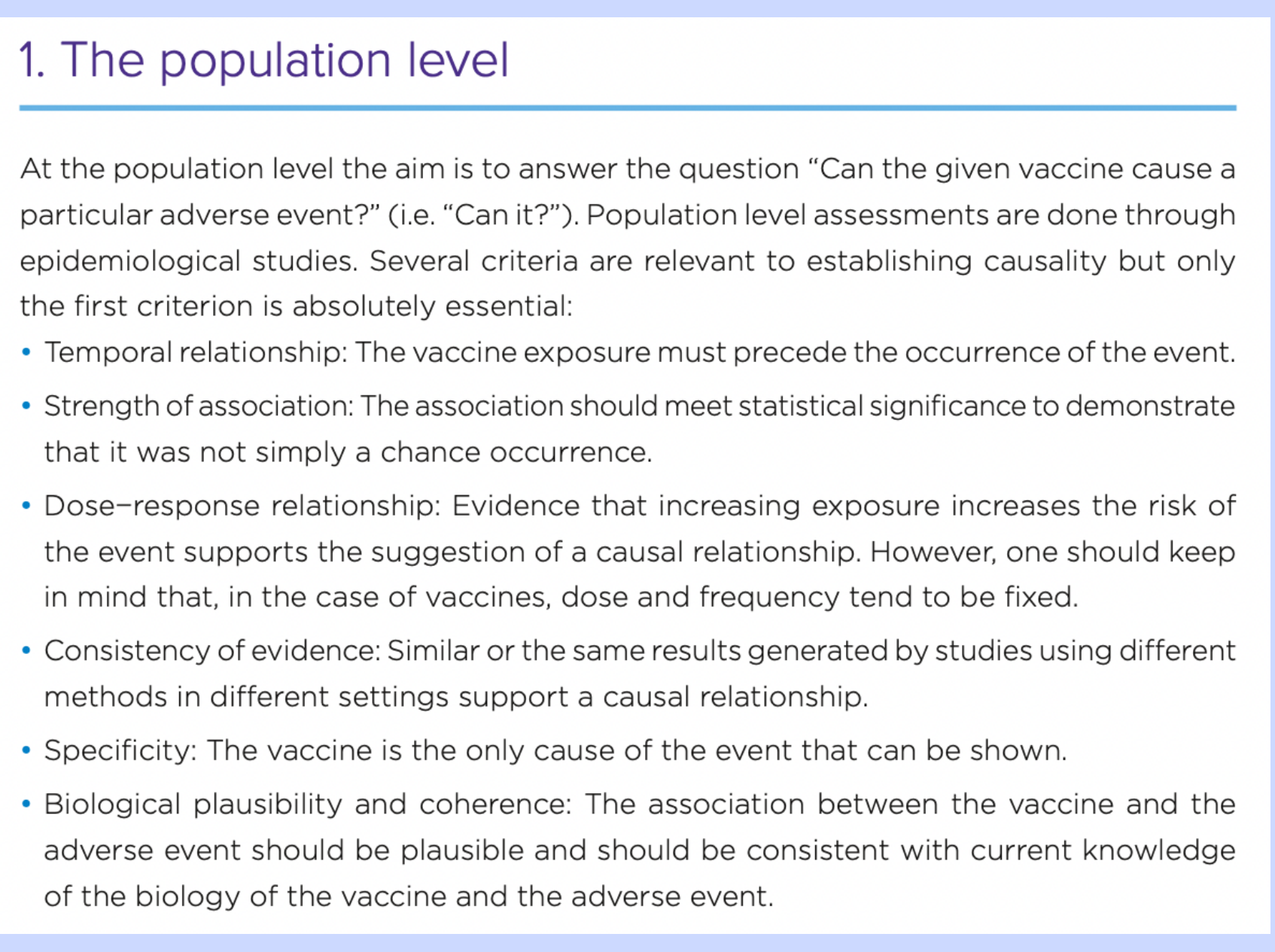
¹AESI = Adverse Event of Special Interest: death, COVID-19 disease, Guillain-Barre Syndrome, seizure, stroke, narcolepsy/cataplexy, anaphylaxis, vaccination during pregnancy, acute myocardial infarction, myopericarditis, coagulopathy, Kawasaki's disease, multisystemic inflammatory syndrome in children
²To determine if results need further clinical review, consider if clinically important, unexpected findings, seriousness, specific syndrome or diagnosis rather than non-specific symptoms
³Will NOT include laboratory results; PRR cut-off for N=5 vs. 0

Figure 1: Table 4.1 Process of monitoring of COVID-19 vaccine adverse events. https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf. Page 20.

WHO - The former has a description of causality assessment protocol that is quite thorough. If you click on the link above, you'll see that it takes you to a book! A book written about how to assess causality from adverse events. It is quite thorough! *They* define an AEFI as the following:

> Adverse event following immunization (AEFI): This is defined as ***any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship*** with the use of the vaccine. The adverse event may be any unfavourable or unintended sign, an abnormal laboratory finding, a symptom or a disease.

They describe therein how to make these assessments both at the individual and the population levels. This is done using several of the Bradford Hill Criteria such as Temporality, Dose response and biological plausibility as shown in Figure 2.


1. The population level

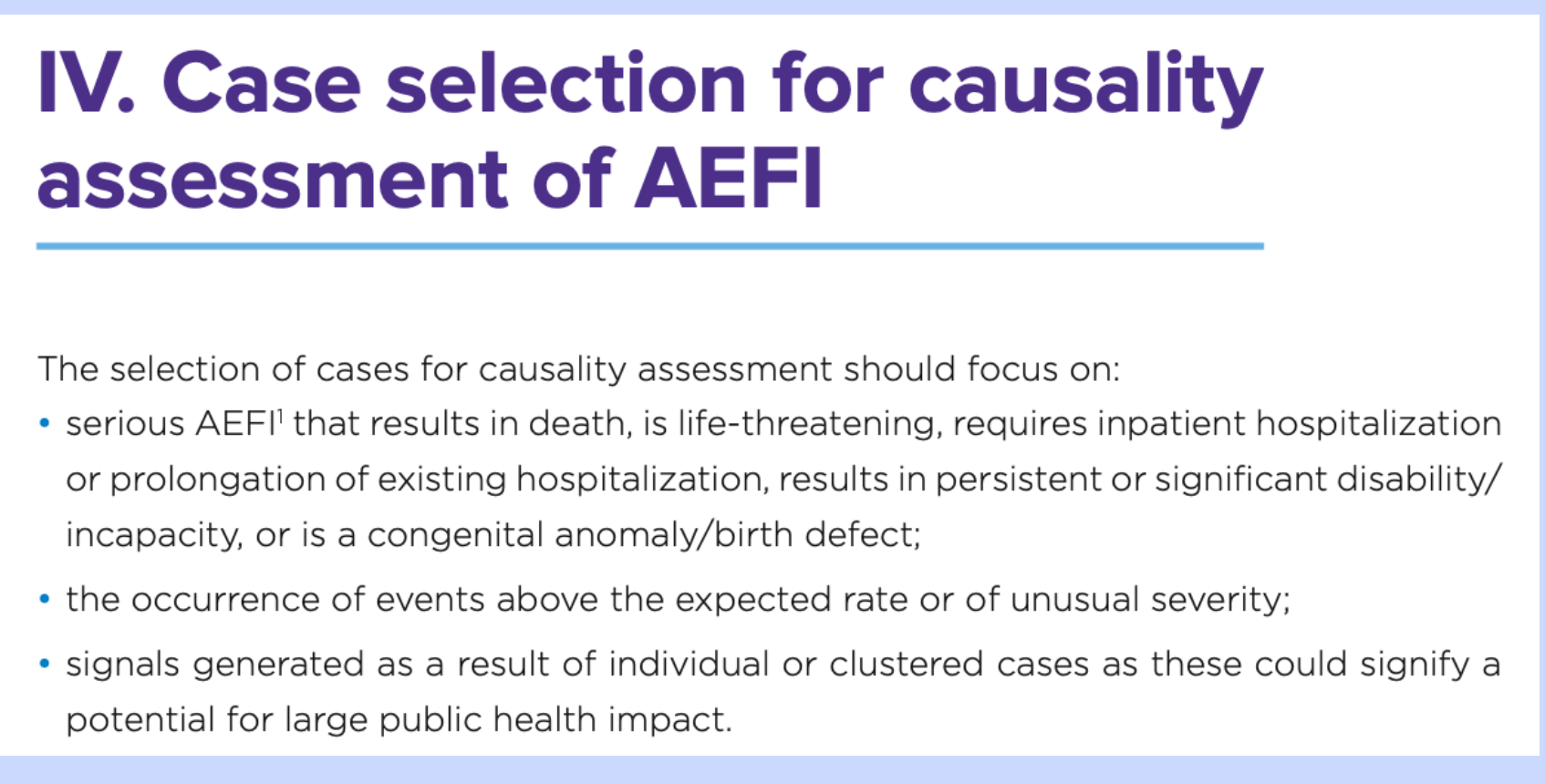
At the population level the aim is to answer the question "Can the given vaccine cause a particular adverse event?" (i.e. "Can it?"). Population level assessments are done through epidemiological studies. Several criteria are relevant to establishing causality but only the first criterion is absolutely essential:

- Temporal relationship: The vaccine exposure must precede the occurrence of the event.
- Strength of association: The association should meet statistical significance to demonstrate that it was not simply a chance occurrence.
- Dose–response relationship: Evidence that increasing exposure increases the risk of the event supports the suggestion of a causal relationship. However, one should keep in mind that, in the case of vaccines, dose and frequency tend to be fixed.
- Consistency of evidence: Similar or the same results generated by studies using different methods in different settings support a causal relationship.
- Specificity: The vaccine is the only cause of the event that can be shown.
- Biological plausibility and coherence: The association between the vaccine and the adverse event should be plausible and should be consistent with current knowledge of the biology of the vaccine and the adverse event.

Figure 2: 6 of the 10 Bradford Hill Criteria for assessment of population level causality likelihood. https://www.who.int/publications/i/item/9789241516990. Page 9.

> Causality assessment usually will not prove or disprove an association between an event and the immunization. ***It is meant to assist in determining the level of certainty of such an association.*** A definite causal association or absence of association often cannot be established for an individual event.

Yes. It is meant to assess whether or not a biological product is doing harm to the public or subpopulations of the public. That's what pharmacovigilance tools like VAERS are for: they represent the epidemiological data set from where the AEFIs are gathered.


IV. Case selection for causality assessment of AEFI

The selection of cases for causality assessment should focus on:

- serious AEFI[1] that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect;
- the occurrence of events above the expected rate or of unusual severity;
- signals generated as a result of individual or clustered cases as these could signify a potential for large public health impact.

Figure 3: This is how they pick the AESIs to assess. https://www.who.int/publications/i/item/9789241516990. Page 15.

As of July 1, 2022, in the context of AEs associated with COVID-19 injectable products reports filed in VAERS *without* considering an URF (URF 10 or 31), there are **32,671** (320,671 - URF 10) deaths, **30,933** (958,923) life threatening reports, **287,731** (8,919,661) hospitalizations, **51,438** (1,594,578) disabilities, **472** (14,632) birth defects reported, **312,839** (9,698,009) severe AEs reported, **63,795** (1,977,645) reports of hepatological AEs, ***46** (460 - URF 10) Creutzfeldt-Jacob disease (CJD) reports*, **4,554** (141,174) reports of spontaneous abortion, **25,910** (803,210) reports of diabetes, **26,402** (818,462) reports of cancer, **37,803** (1,171,893) reports of myocarditis and **79,936** (2,478,016) reports of thrombotic AEs, just to name a few clustered cases in VAERS. By the way, that CJD count is above the background reporting rate for the year. It is very concerning.

I think we have a Case.

The following is a screenshot of the WHO Causality assessment algorithm schematic on page 36 of **Causality assessment of an adverse event following immunization** (**AEFI**)**: user manual for the revised WHO classification, 2nd ed., 2019 update**, that was sent with the FOIA request.

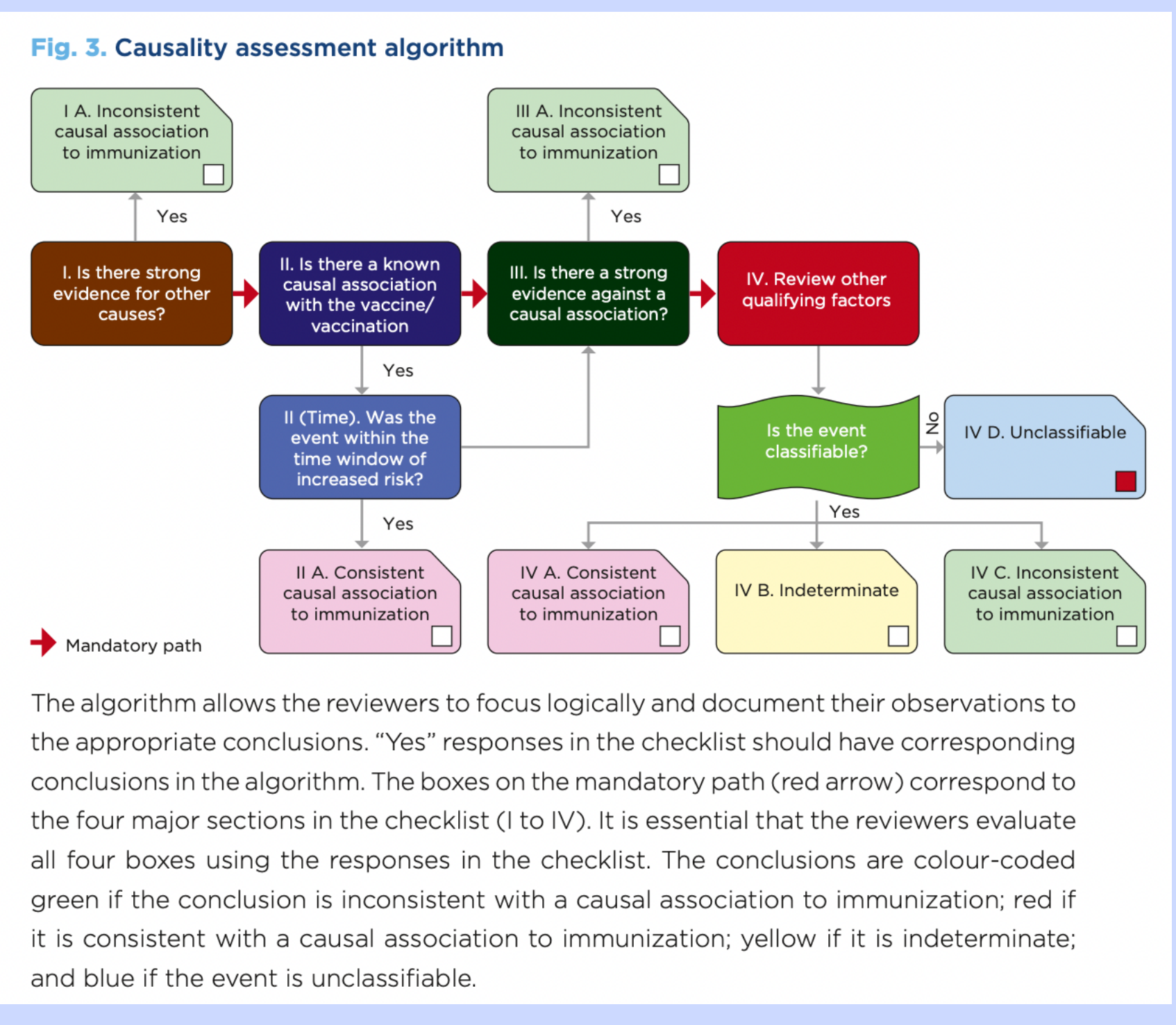


Fig. 3. Causality assessment algorithm
I A. Inconsistent causal association to immunization ☐
III A. Inconsistent causal association to immunization ☐
Yes
Yes
I. Is there strong evidence for other causes?
II. Is there a known causal association with the vaccine/vaccination
III. Is there a strong evidence against a causal association?
IV. Review other qualifying factors
Yes
II (Time). Was the event within the time window of increased risk?
Is the event classifiable?
No
IV D. Unclassifiable
Yes
Yes
II A. Consistent causal association to immunization ☐
IV A. Consistent causal association to immunization ☐
IV B. Indeterminate ☐
IV C. Inconsistent causal association to immunization ☐
Mandatory path

The algorithm allows the reviewers to focus logically and document their observations to the appropriate conclusions. "Yes" responses in the checklist should have corresponding conclusions in the algorithm. The boxes on the mandatory path (red arrow) correspond to the four major sections in the checklist (I to IV). It is essential that the reviewers evaluate all four boxes using the responses in the checklist. The conclusions are colour-coded green if the conclusion is inconsistent with a causal association to immunization; red if it is consistent with a causal association to immunization; yellow if it is indeterminate; and blue if the event is unclassifiable.

Figure 4: Causality assessment algorithm of the WHO. https://www.who.int/publications/i/item/9789241516990. Page 36.

Just so everyone knows, they have used (and do use) VAERS data as the source data for this causality assessment protocol, in the past. In the example in Figure 5, they found no causal link between MMR shots and death reports in VAERS for kids. Of course they didn't. That would halt the program.

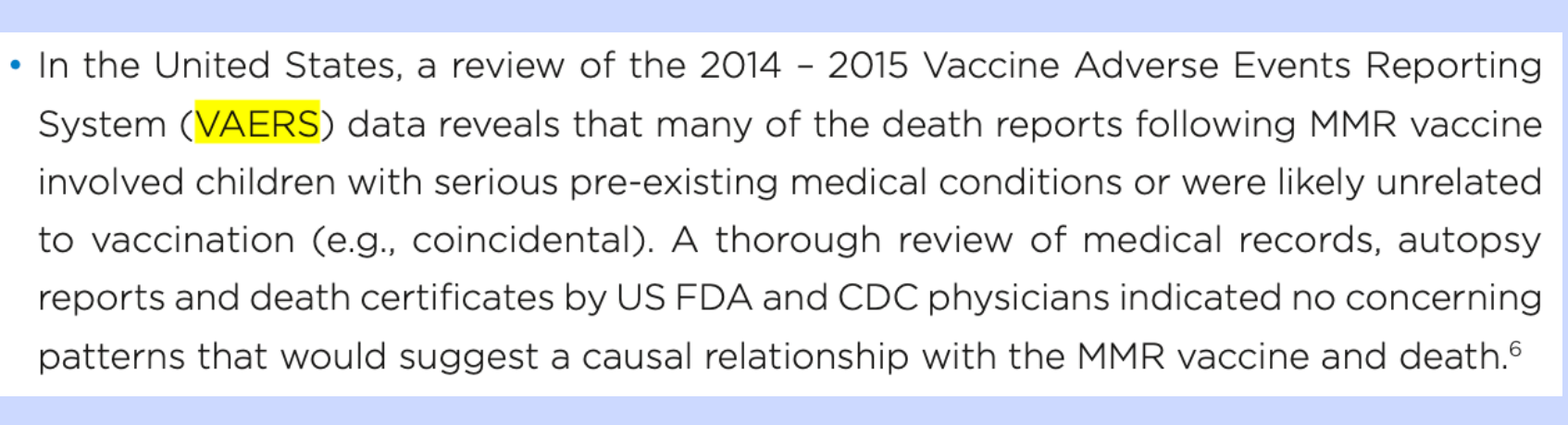
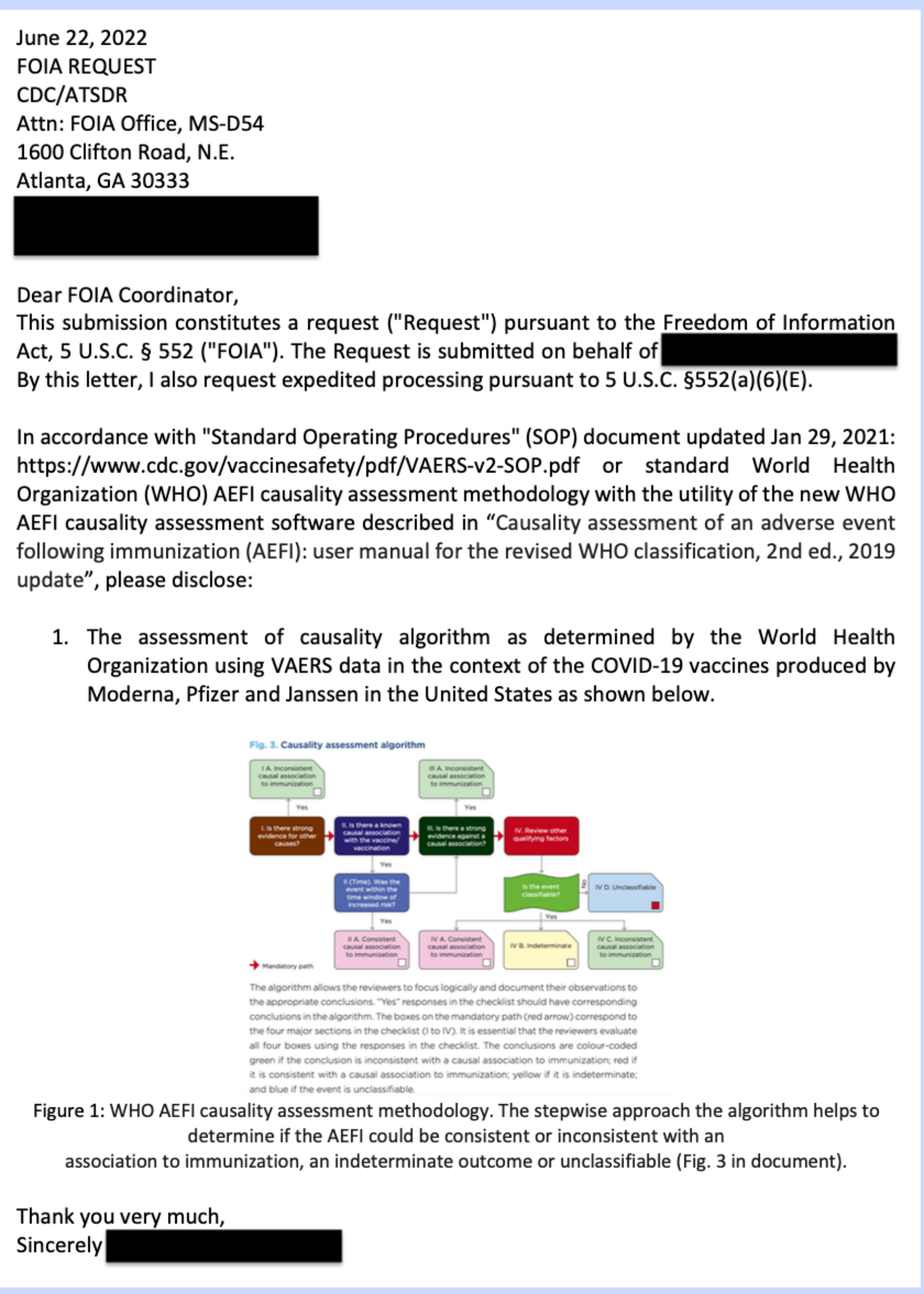

- In the United States, a review of the 2014 – 2015 Vaccine Adverse Events Reporting System (VAERS) data reveals that many of the death reports following MMR vaccine involved children with serious pre-existing medical conditions or were likely unrelated to vaccination (e.g., coincidental). A thorough review of medical records, autopsy reports and death certificates by US FDA and CDC physicians indicated no concerning patterns that would suggest a causal relationship with the MMR vaccine and death.[6]

Figure 5: Causality assessment of VAERS death associated with MMR. https://www.who.int/publications/i/item/9789241516990. Page 24.

So the FOIA request itself is valid, in my opinion. Here is the FOIA request letter.


June 22, 2022
FOIA REQUEST
CDC/ATSDR
Attn: FOIA Office, MS-D54
1600 Clifton Road, N.E.
Atlanta, GA 30333
[redacted]

Dear FOIA Coordinator,
This submission constitutes a request ("Request") pursuant to the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"). The Request is submitted on behalf of [redacted]
By this letter, I also request expedited processing pursuant to 5 U.S.C. §552(a)(6)(E).

In accordance with "Standard Operating Procedures" (SOP) document updated Jan 29, 2021: https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf or standard World Health Organization (WHO) AEFI causality assessment methodology with the utility of the new WHO AEFI causality assessment software described in "Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification, 2nd ed., 2019 update", please disclose:

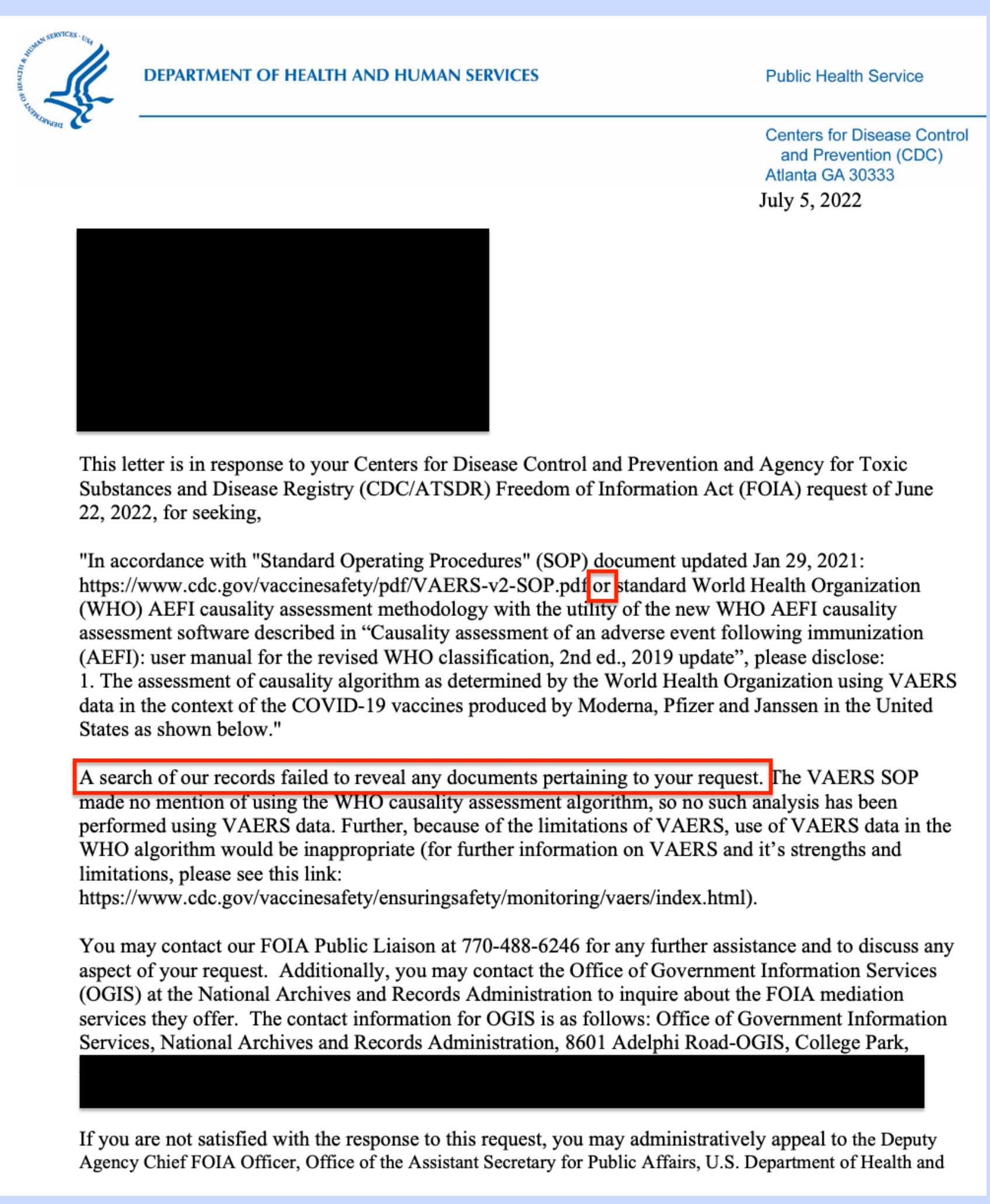
1. The assessment of causality algorithm as determined by the World Health Organization using VAERS data in the context of the COVID-19 vaccines produced by Moderna, Pfizer and Janssen in the United States as shown below.

Figure 1: WHO AEFI causality assessment methodology. The stepwise approach the algorithm helps to determine if the AEFI could be consistent or inconsistent with an association to immunization, an indeterminate outcome or unclassifiable (Fig. 3 in document).

Thank you very much,
Sincerely [redacted]

Figure 6: The FOIA request made June 22, 2022.

Here is the expedient reply from the Department of Health and Human Services.


DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333
July 5, 2022

[redacted]

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of June 22, 2022, for seeking,

"In accordance with "Standard Operating Procedures" (SOP) document updated Jan 29, 2021: https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf or standard World Health Organization (WHO) AEFI causality assessment methodology with the utility of the new WHO AEFI causality assessment software described in "Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification, 2nd ed., 2019 update", please disclose:
1. The assessment of causality algorithm as determined by the World Health Organization using VAERS data in the context of the COVID-19 vaccines produced by Moderna, Pfizer and Janssen in the United States as shown below."

A search of our records failed to reveal any documents pertaining to your request. The VAERS SOP made no mention of using the WHO causality assessment algorithm, so no such analysis has been performed using VAERS data. Further, because of the limitations of VAERS, use of VAERS data in the WHO algorithm would be inappropriate (for further information on VAERS and it's strengths and limitations, please see this link: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html).

You may contact our FOIA Public Liaison at 770-488-6246 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park,
[redacted]

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and

Figure 6: The FOIA request response made July 5, 2022.

I can imagine that there might be some crafty word play at play here to side-step disclosing the information requested in the request. Or perhaps the request should have been more specific? Or less specific? Or perhaps the inclusion of the algorithm itself was a mistake? Or perhaps specifically requesting this causality assessment using *VAERS data* was the mistake? It is noteworthy, however, that the word 'or' was used to imply that the search should be made pertaining to both documents separately, but perhaps since the causality algorithm itself is associated with the WHO and not the SOP, it might understandable that they came up with nothing… ?

But still.

WHO's doing the causality assessment? (Get it?)

Notice, that they did point the FOIA requester to the VAERS website to remind said requester that VAERS isn't actually used for anything useful and remains the duck decoy for the fact that vaccine companies remain liable-less.

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18 Comments

Write a comment…

Jessica Rose Jul 5 Author

A comment from a great colleague: "The FOIA was too specific and gave them a get out of jail free card. It needs to be resubmitted with something like "Please disclose in detail CDCs methodology for determining causality, including any protocols or standard operating procedures. Please disclose the results from all analyses conducted under those methods, protocols or procedures." Learning all the time. I love Substack.

34 Reply Collapse

1 reply

steveBDH Jul 5

They are creating hell on earth for a lot of innocent people. We do not need an algorithm to realize how many people have been killed or injured by the horrible mRNA trash shots. All the honest warriors are telling mankind to stop; not enough people are listening and they cannot wrap their heads around the extent of the evil behind this crap. Thank you Dr. Rose. You are a warrior.

24 Reply Collapse

16 more comments…

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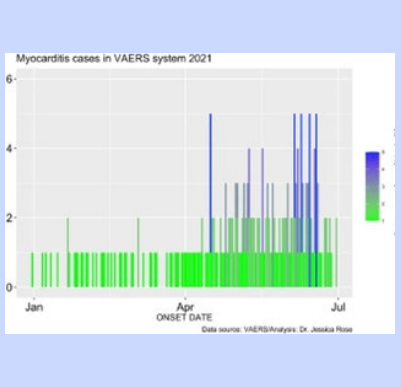
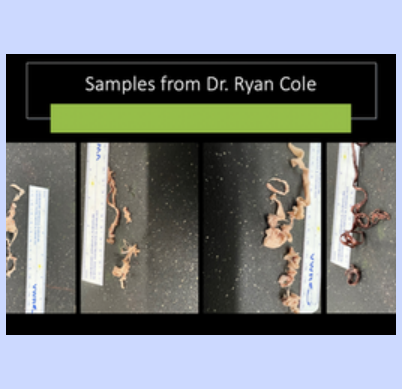
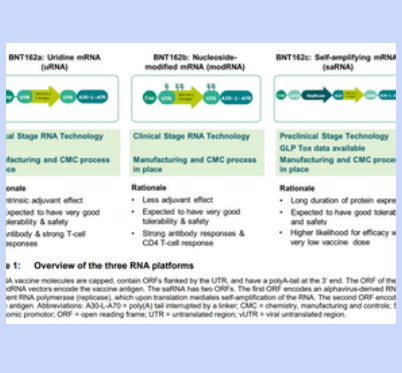

A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable…
Jessica Rose PhD, MSc, BSc and Peter A. McCullough MD, MPH
JESSICA ROSE NOV 2, 2021 1,195 141


Rewrite: Let's tag team this until everybody understands
The modified spike protein is dangerous and for very specific reasons.
JESSICA ROSE JUN 13 594 147


When you hear BNT162c(2), run, don't walk, RUN away.
It's already in the clinical 'trials'
JESSICA ROSE JUN 19 471 95

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